REMARKS

Claims 32-115 are pending in the instant application. Claims 38 and 63-70 have been cancelled as being drawn to the non-elected invention. Claims 46-49 and 115 are allowed. Claims 32-37, 39-41, 43-45, 50-62, and 71-114 stand rejected. Claim 42 has been objected to. Applicant herein cancels claims 38, and 63-70 without prejudice, amends claims 32, 39-42 and 71-92, and adds claims 32-39 to clarify the present invention. Applicant has amended the specification to correct typographical errors. These amendments find support in the as-filed specification and claims. No new matter is introduced by the above amendments to the specification or the claims.

In view of the following amendment and response, the Applicants believe the claims presented herein are allowable. Reconsideration is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

CLAIM OBJECTIONS

Claim 42 is objected to under 37 C.F.R. 1.75(c) as being in improper form because a multiple dependent claim must refer to the multiple dependent claim from which it is depending in the alternative form. In addition, claims 53, 71, 82, 93, and 104 are objected to for depending from claim 42. Claim 42 has been amended to the alternative form thus rendering the objection moot. Similarly, the objection to claims 53, 71, 82, 93, and 104 should be withdrawn.

REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 32-37 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner alleges that the specification teaches that the

immunostimulants of the invention include plant-derived saponins. page 5, lines 17-21. The Examiner also alleges that the specification does not teach any reason for the exclusion of saponins from the meaning of the words immunostimulants in the claims.

Applicants respectfully traverse the rejection of these claims. An inventor only need to support what he claimed in the application. He does not need to support what is not claimed. See *Engel Insustries, Inc. v. Lockformer Co.*, 946 F.2d 1528, 1531, 20 U.S.P.Q.2d 1300, 1302 (Fed. Cir. 1991) (only the inventions defined by the claims need be explained in the patent application in a manner sufficient to be supported as required by 35 U.S.C. §112, first paragraph). Therefore, a proviso excluding certain immunostimulants from the claimed invention need not be expressly supported in the specification.

Furthermore, Applicants disclose that immunostimulants in the present inventions can be bacterially derived compounds and derivatives thereof and plant derived compounds and derivative thereof. See page 5, lines 26-31 of the specification. This disclosure indicates that the immunostimulants of the present invention may be derived from either group of compounds or both. Applicants also provide a description of monophosphoryl lipid A, a bacterially derived compound with adjuvant activity and indicate that monophosphoryl lipid A can be used as an immunostimulant in the present invention. See page 6, lines 1-13 of the specification. By describing bacterially derived immunostimulants as a preferred component of the present invention, Applicants have disclosed the invention in such a manner as to indicate the exclusion of saponins from the meaning of the word immunostimulants.

As claims 33-37 depend from claim 32, rejection of these claims under 35 U.S.C. §112, first paragraph should be withdrawn.

The Applicants respectfully submit that in view of the forgoing remarks and the claims as amended, the Applicants have overcome the Examiner's rejection under 35 U.S.C. §112, first paragraph, and that rejection should be withdrawn.

REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 32-37, 39-41, and 43-45, 50-62, and 71-114 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner alleges that the claims as written may have multiple interpretations. Specifically, the Examiner indicates that one of ordinary skill in the art may interpret the phrase "other antigen" as antigens other than those identified components of the vaccine or antigens other than immunostimulants.

Applicants have amended the claims to address the Examiner's rejections. Claims 32 and 39 now recite that an immunostimulant may be a "first antigen." In addition, claims 32 and 39 no longer refer to "other antigens," and claim 39 recites a "second antigen" as part of the claim. Furthermore, Applicants have amended claims 40-42 and 71-92, which depend from either claim 32 or 39 either directly or indirectly to recite a "second antigen." Support for these amendments is provided on page 2, line 31 to page 3 lines 1-15 of the specification.

The Applicants respectfully submit that in view of the forgoing remarks and the claims as amended, the Applicants have overcome the Examiner's rejection under 35 U.S.C. §112, second paragraph, and that rejection should be withdrawn.

NEW CLAIMS

Applicants have added claims 116-119 to the application. New claim 116 is directed to an adjuvant comprising an immunostimulant absorbed onto a metal salt particle. This claim is supported on page 3, lines 7-9 and 5, lines 26- 31 of the specification. New claim 117 is directed to a process for making a vaccine composition wherein an adjuvant comprising an

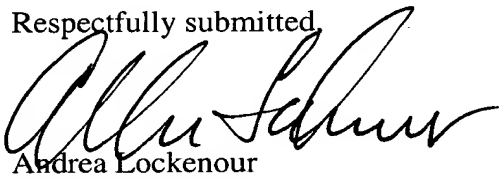
immunostimulant on a metal salt is admixed with an antigen. Support for this claim can be found on page 3, lines 10-15 and page 5, lines 26-31.

New claim 118 is directed to an adjuvant comprising an immunostimulant absorbed onto an metallic salt. Support for this claim can be found on page 2, line 32 through page 3, lines 1-2. New claim 119 is directed to process for the manufacture of a vaccine comprising an adjuvant comprising an immunostimulant on a metallic salt and an antigen. Support for this claim can be found on page 3, lines 11-13.

Applicants reserve the right to prosecute, in one or more patent applications, the claims to non-elected inventions, the claims as originally filed, and any other claims supported by the specification. The Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration and allowance of the pending claims is earnestly solicited.

If it would expedite the prosecution of this application, the Examiner is invited to confer with the Applicants' undersigned agent.

Respectfully submitted,



Andrea Lockenour
Agent for Applicants
Registration No. 51,962

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-7568
Facsimile (610) 270-5090
N:\AVL\patapps\B45158\Roa1B45158.doc

Serial No.: 09/807,657
Group Art Unit No.: 1648

Version with Markings to Show Changes Made

In the Specification:

Please replace the paragraph beginning at page 4, line 3, with the following rewritten paragraph:

-- The definition of substantially free of other antigens, in relation to this invention, is where not more than 20% by mass of the total material capable of adsorbing to the particle of metallic salt is an other antigen, preferably not more than 10%, and most preferably not more than 5%. Alternatively, the substantially free [at]of immunostimulant, in relation to this invention, is where not more than 20% by mass of the total material capable of adsorbing to the particle of metallic salt is immunostimulant, preferably not more than 10%, and most preferably not more than 5%. Routine assays, apparent to the man skilled in the art, could be used to determine whether the antigen and immunostimulant, are adsorbed onto different discrete particles, including but not limited to separation of the vaccine into distinct fractions by free flow of the formulation within an electric field, or techniques such as sedimentation rate analysis which are particularly suited to non-particulate antigens, followed by assaying for the immunostimulant or antigen in the fractions.--

In the Claims:

Please cancel claims 38, and 63-70 without prejudice as being drawn to the non-elected invention. Please amend Claims 32, 39-42 and 71-92 as follows:

32. (Amended) An adjuvant composition comprising an immunostimulant adsorbed onto a first metallic salt particle, wherein the immunostimulant may be a first antigen and [characterised in that the]the first metallic salt particle is substantially free of any antigen other than said first antigen where present and in that the immunostimulant is not a saponin derived from the bark of Quillaja Saponaria Molina.

39. (Amended) A process for the manufacture of a vaccine composition comprising the admixture of a) an adjuvant composition comprising an immunostimulant adsorbed onto a first metallic salt particle, wherein the immunostimulant may be a first antigen [characterised in that the]and the first metallic salt particle is substantially free of [other antigen] any antigen other than the first antigen where present, and b) a second [an]antigen wherein the first antigen and the second antigen may be the same.

40. (Amended) A process for the manufacture of a vaccine composition as claimed in claim 39, wherein[characterised in that] the second antigen is adsorbed onto a second metallic salt particle wherein the metallic salt of each of the first metallic salt particle and the second metallic salt particle may be the same.

41. (Amended) A process as claimed in claims 39, wherein the second antigen is selected from the group comprising: antigens derived from Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex Virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, IgE peptides, Der p1, pollen related antigens; or Tumor associated antigens (TAA), MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRh (GnRH), CEA, PSA, KSA, or PRAME.

42. (Amended) A vaccine composition comprising an adjuvant composition according to any one of claims 32 to 37[38], additionally comprising a[n] second antigen wherein the first antigen and the second antigen may be the same.

71. (Amended) A vaccine composition as claimed in claim 42, wherein the second antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B. C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer

associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH(GnRH), CEA, PSA, tyrosinase, Survivin, KSA, or PRAME.

72. (Amended) A vaccine composition as claimed in claim 43, wherein the second antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B. C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH(GnRH), CEA, PSA, tyrosinase, Survivin, KSA, or PRAME.

73. (Amended) A vaccine composition as claimed in claim 44, wherein the second antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B. C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH(GnRH), CEA, PSA, tyrosinase, Survivin, KSA, or PRAME.

74. (Amended) A vaccine composition as claimed in claim 45, wherein the second antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B. C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH(GnRH), CEA, PSA, tyrosinase, Survivin, KSA, or PRAME.

75. (Amended) A vaccine composition as claimed in claim 46, wherein the second antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus,

Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B. C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH(GnRH), CEA, PSA, tyrosinase, Survivin, KSA, or PRAME.

76. (Amended) A vaccine composition as claimed in claim 47, wherein the second antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B. C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH(GnRH), CEA, PSA, tyrosinase, Survivin, KSA, or PRAME.

77. (Amended) A vaccine composition as claimed in claim 48, wherein the second antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B. C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH(GnRH), CEA, PSA, tyrosinase, Survivin, KSA, or PRAME.

78. (Amended) A vaccine composition as claimed in claim 49, wherein the second antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B. C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer

associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH(GnRH), CEA, PSA, tyrosinase, Survivin, KSA, or PRAME.

79. (Amended) A vaccine composition as claimed in claim 50, wherein the second antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B. C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH(GnRH), CEA, PSA, tyrosinase, Survivin, KSA, or PRAME.

80. (Amended) A vaccine composition as claimed in claim 51, wherein the second antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B. C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH(GnRH), CEA, PSA, tyrosinase, Survivin, KSA, or PRAME.

81. (Amended) A vaccine composition as claimed in claim 52, wherein the second antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B. C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH(GnRH), CEA, PSA, tyrosinase, Survivin, KSA, or PRAME.

82. (Amended) A vaccine composition as claimed in claim 71, wherein the second antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

83. (Amended) A vaccine composition as claimed in claim 72, wherein the second antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

84. (Amended) A vaccine composition as claimed in claim 73, wherein the second antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

85. (Amended) A vaccine composition as claimed in claim 74, wherein the second antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

86. (Amended) A vaccine composition as claimed in claim 75, wherein the second antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

87. (Amended) A vaccine composition as claimed in claim 76, wherein the second antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

88. (Amended) A vaccine composition as claimed in claim 77, wherein the second antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

89. (Amended) A vaccine composition as claimed in claim 78, wherein the second antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

90. (Amended) A vaccine composition as claimed in claim 79, wherein the second antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

91. (Amended) A vaccine composition as claimed in claim 80, wherein the second antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

92. (Amended) A vaccine composition as claimed in claim 81, wherein the second antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.